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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,036	01/11/2001	Ekkehard Leberer	0116696-13	8288
29180 7590 11/27/2007 BELL, BOYD, & LLOYD LLP P.O. BOX 1135 CHICAGO, IL 60690			EXAMINER JOIKE, MICHELE K	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 11/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/758,036

Applicant(s)

LEBERER ET AL.

Examiner

Michele K. Joike, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-10,20 and 21 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed September 10, 2007. Claims 1-10, 20 and 21 are pending and examined. Any rejection of record in the previous Office Action, mailed April 11, 2007, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6 –10, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US20030165806 (hereinafter Pausch) in view of US 5,795,770 (hereinafter Gaber) in further view of Fairman et al.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over US20030165806 (hereinafter Pausch) in view of US 5,795,770 (hereinafter Gaber), in view of Fairman et al, and in further view of Rampe et al.

Response to Arguments Concerning Claim Rejections – 35 USC § 103

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Applicant's arguments filed September 10, 2007 have been fully considered and are not found persuasive for the following reasons.

The following grounds of traversal are presented:

Fariman et al teach triple mutant yeast cells that grow less well than double mutants, and are difficult to grow, maintain and manipulate, and that the cells are too fragile, which would teach away from mutating it further. Furthermore, Fairman et al are silent on the use of the triple mutant in a screening assay for any potassium channel, and they state that the role of TOK1 in wildtype yeast cells remains unclear and requires further investigation.

Applicant argues that the disclosure of their specification indicates that human potassium ion channels HERG1 and Kv1.5 were unable to complement the *trk1-trk2*-strain, and therefore one of skill in the art would presume that they would be equally unable to complement the *tok1-trk1-trk2*-triple mutant owing to its more pathogenic phenotype. Applicant argues that this finding abolishes any motivation to test any eukaryotic potassium ion channel in the *tok1-trk1-trk2*-triple mutant, because it represents an unexpected and surprising result.

Rampe does not cure the deficiencies of Pausch, Gaber and Fairman et al.

Applicants' arguments are not found persuasive for the following reasons.

There is no evidence that the $\Delta trk1$, $\Delta trk2$ and $\Delta tok1$ mutant is too fragile in Fariman et. al; there is no teaching away from mutating it further. Fariman et al report

that the triple mutant grows less well than the *trk1* Δ *trk2* Δ double mutant, but that is to be expected of a strain that has an additional mutation.

Fairman et al may be silent on the use of the triple mutant in a screening assay for a human potassium channel; however, when combined with Pausch and Gaber, they do teach the use of the triple mutant in a screening assay for a human potassium channel. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Fairman et al stated that that they have "shown unambiguously that TOK1 is capable of passing inward K⁺ current in vivo." (p. 156, last paragraph). All that is needed to be known about TOK1 is that it is a K⁺ channel.

The knowledge that neither HERG1 nor Kv1.5 were able to complement the *trk1-trk2*- strain was not common knowledge to the skilled artisan prior to the instant invention; as such, this information could not have prevented the ordinary skilled artisan from being motivated to combine the teachings of Pausch, Gaber and Fairman et al because it was unknown to that same ordinary skilled artisan when the combination would have been made. There are indeed eukaryotic potassium ion transporters that can complement the *trk1-trk2*- strain, as is obvious from the fact that gplRK1 in the very least does so, as taught by Tang (see for example the Abstract, cited in prior actions), and that the triple deletion has a more compromised phenotype than the

double deletion (as taught by Fairman et al). Therefore, the ordinary skilled artisan would at least be motivated to combine the teachings of the indicated references to arrive at the invention insofar as it related to the gplRK1 potassium ion channel even in view of Applicant's arguments concerning the non-complementation of HERG1 and Kv1.5.

Second, the presumption that a protein (such as HERG1 or Kv1.5) would be unable to rescue a triple deletion strain, simply because it was unable to rescue a double deletion strain, is not scientifically sound. The ordinary skilled artisan can easily envision a situation where the Tok1 protein would interfere with the activity of HERG1 or Kv1.5 by competing for one or more co-factors required for activity, thereby negating the activity of either or both proteins and resulting in the absence of complementation. When envisioning this plausible situation, the skilled artisan would be even more motivated to use the triple deletion strain in order to ensure that the Tok1 protein was not acting in an interfering capacity with regard to the HERG1 and/or Kv1.5 proteins. Indeed, the argument presented by Applicant seems to contradict their own findings that HERG1 and Kv1.5 were unable to rescue the double mutant strain while being able to rescue the triple mutant strain. Significantly, regarding Applicant's assertion that the double deletion strain is worse than the triple deletion strain, this result directly contradicts the teachings of the prior art (Fairman et al), for which Applicant provides no explanation.

Finally, even if one of ordinary skill in the art were to accept Applicant's allegation that non-complementation of a double deletion strain by HERG1 nor Kv1.5 would

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abrogate any motivation to test these proteins in a triple deletion strain, Applicant's argument amounts to an "unexpected results" argument which requires that the claims in question be commensurate in scope with the unexpectedness of the result (see for example MPEP § 716.02(d)[R-1]). In order for such an argument to be valid, the argument must be commensurate in scope with the claimed invention. This is clearly not the instant case since the invention concerns the testing of more than just HERG1 and Kv1.5 in a *tok1-trk1-trk2* triple mutant. Indeed, as set forth above, the fact that neither HERG1 nor Kv1.5 complements the double deletion strain (as alleged by Applicant) does not correlate to the non-complementation of any other eukaryotic potassium ion channel in the double deletion strain. Such a presumption is in fact disproved by the fact that at least one potassium ion channel, *gplRK1*, *did* in fact complement the double deletion strain (as taught by Tang). Thus, it is clear that the unexpected results that Applicant relies upon as an argument are not commensurate in scope with the instantly rejected claims.

As to the argument of Rampe, the Examiner contends that there are no deficiencies to cure.

Allowable Subject Matter

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nancy T. Vogel/
Primary Examiner, Art Unit 1636

Michele K Joike, Ph.D.
Examiner
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